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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,454

09/26/2006

Michael Kretschmar

LNK-021

9476

31496

7590

09/10/2009

SMITH PATENT CONSULTING, LLC
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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

NOTIFICATION DATE

DELIVERY MODE

09/10/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chalin@smithpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,454	KRETSCHMAR ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-17 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-17 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 4-17 and 25-27 are pending.

Applicants' amendment filed May 30, 2009 is acknowledged. Applicants' response has been fully considered. Claims 4-9 and 11-17 have been amended, claims 1-3 and 21-24 have been cancelled, and new claims 25-27 have been added. Therefore, claims 4-17 and 25-27 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1-17 and 23-24 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment of the claims, applicants' cancellation of the claims, and applicants' response at pages 7-8 in the amendment filed May 30, 2009.

Withdrawn Claim Rejections - 35 USC § 102

3. The previous rejection of claims 1-3, 5, 6, 11 and 21 under 35 U.S.C. 102(b) as being anticipated by Gorman *et al.* (Thrombosis Research 12, 341-352 (1978)), is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claims, and applicants' response at pages 8-10 in the amendment filed May 30, 2009.
4. The previous rejection of claims 21-24 under 35 U.S.C. 102(b) as being anticipated by Burnouf-Radosevich *et al.* (Vox Sanguinis 62, 1-11 (1992)), is withdrawn in view of applicants' cancellation of the claims, and applicants' response at page 8 in the amendment filed May 30, 2009.

Withdrawn Claim Rejections -Obviousness Type Double Patenting

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5. The previous rejection of claims 1-3 and 21-23, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 and 22-23 of co-pending application 10/594,455, is withdrawn in view of applicants' cancellation of the claims in the amendment filed May 30, 2009.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 25-27 are directed to a method of separating a VWF having a high activity from a VWF having a low specific activity using hydroxyapatite chromatography, comprising binding VWF to a hydroxyapatite column matrix, washing out VWF having a specific activity less than 70 U per mg VWF antigen, and eluting a VWF having a specific VWF activity greater than 120 U per mg VWF antigen.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other

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materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification indicates that in wash step (b), the hydroxylapatite matrix is washed with a buffer having a medium salt concentration, such as at the total concentration of sodium and/or potassium phosphate being 100 to 300 mM, preferably 200 to 300 mM, more preferably 200 to 270 mM, most preferably 210 to 250 mM, where VWF having a low specific VWF activity is washed out; and that in step (c), VWF having a high specific VWF activity can be eluted with a buffer having a relatively high salt concentration, such as 200 to 500 mM, preferably 250 to 500 mM, more preferably 300 to 400 mM, sodium and/or potassium phosphate (page 5, lines 10-18), the specification does not disclose a genus of variants for salts having concentrations ranging from 100-300 mM in step (b) and salts having concentrations ranging from 200-500 mM in step (c). A single species of sodium or potassium phosphate with concentrations ranging from 100-300 mM in step (b) and with concentrations ranging from 200-500 mM in step (c) does not provide sufficient written description for a genus of salt variants

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since there is substantial variation in the whole genus of salt variants. The lack of description on the genus of variants of salts used in the claimed method and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4-6 and 8-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 4-6 and 8-17 are indefinite as to under what conditions the VWF having low specific VWF activity would be washed out and the VWF having high specific VWF activity would be eluted out from a hydroxylapatite column. Claims 5-6 and 8-17 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 4-17 and 25-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of co-pending application 10/594,455 (based on preliminary amendment filed 9/26/2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 4-17 and 25-27 in the instant application discloses a method of separating a VWF having a high activity from a VWF having a low specific activity using hydroxyapatite chromatography, comprising binding VWF to a hydroxyapatite column matrix, washing out VWF having a specific activity less than 70 U per mg VWF antigen, and eluting a VWF having a specific VWF activity greater than 120 U per mg VWF antigen. This is obvious variation in view of claims 1-20 of the co-pending which discloses a method of purifying VWF by carrying out at least one hydroxyapatite chromatography, and the method may further use a separate hydroxyapatite chromatography to bind VFW, to wash out protein impurities, and then to elute the VFW with high activity. Both the claims of instant application and the claims of the co-pending application are directed to a method of purifying VWF by carrying out at least one hydroxyapatite chromatography, and the method uses a separate hydroxyapatite chromatography to bind VFW and then to elute the VFW with high activity. Thus, claims 4-17 and 25-27 in present application and claims 1-20 of the co-pending are obvious variations of a method of purifying VWF by

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carrying out at least one hydroxyapatite chromatography, and the method uses a separate hydroxyapatite chromatography to bind VFW and then to elute the VFW with high activity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants do not respond to the rejection.

Conclusion

10. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

September 7, 2009